Group II, claim(s) 25, drawn to the special technical feature of a chimeric protein comprising a protein transducing domain, a deaminase domain comprising a CTD-1, and an anchor oligonucleotide.

Group III, claim(s) 26, drawn to the special technical feature of a CEM15 mimetic.

Group IV, claim(s) 28, drawn to the special technical feature of a method of interrupting HIV infectivity comprising contacting an HIV-infected cell or a cell prior to HIV infection with a chimeric protein comprising a protein transduction domain and a deaminase domain.

Group V, claim(s) 29-32, drawn to the special technical feature of a method of treating a subject with an HIV infection or at risk for an HIV infection comprising administering to the subject an effective amount of the chimeric protein comprising a protein transduction domain and a deaminase domain.

Group VI, claim(s) 33-35 and 66-77, drawn to the special technical feature of an isolated nucleotide sequence that encodes the chimeric protein comprising a protein transduction domain and a deaminase domain; a vector comprising the nucleotide sequence; and a recombinant host cell comprising the vector.

Group VII, claim(s) 37-46, drawn to the special technical feature of a method of screening for a deaminase mimetic.

Group VIII, claim(s) 78, drawn to the special technical feature of an isolated B lymphoblastic cell or other receptive cell which has taken up the chimeric protein

comprising a protein transduction domain and a deaminase domain.

Group IX, claim(s) 79-97, drawn to the special technical feature of a method of inducing production of immunoglobulins in a B lymphocyte cell.

Group X, claim(s) 98-110 and 118-120, drawn to the special technical feature of a method of inducing an immune response in a subject comprising administering the chimeric protein comprising a protein transduction domain and a deaminase domain.

Group XI, claim(s) 111-117, drawn to the special technical feature of a method of treating a subject comprising administering a population of B lymphocyte cells that have taken up the chimeric protein comprising a protein transduction domain and a deaminase domain.

In response, applicants elect Group X, claims 98-110 and 118-120, with traverse.

Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Action has not shown that a serious burden would be required to examine all of the pending claims of Groups I-XI in the this application. Specifically, M.P.E.P § 803 provides:

> If the search and examination of an application can be made without serious burden, the Examiner *must* examine it on the merits, even though it includes claims to distinct or independent inventions. *(Emphasis supplied.)*

Thus, for a restriction to be proper, the Office Action must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that

the search and examination of the entire application cannot be made without serious burden. See M.P.E.P § 803.

The Office Action has not shown that the second requirement has been met. Specifically, the Office Action has not shown that it would be a serious burden to search and examine all of the groups together. Indeed, the Office Action has not even alleged that it would be a serious burden to search and examine all of the groups together. Consequently, reconsideration and modification or withdrawal of the restriction is requested.

Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Restriction Requirement does not meet the requisite burden for establishing a lack of unity of invention. Specifically, 37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. PCT Rule 13.2 states that

> [T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Thus, the requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features, which define a contribution that the claimed subject

matter makes over the prior art. Additionally, MPEP 1850 states that contributions over the prior art "should be considered with respect to novelty and inventive step."

Applicant respectfully disagrees with the Action's statement that the claimed invention is known in the art. To the contrary, the pending claims are patentable over the cited references. The Examiner is attempting to combine a reference that teaches an APOBEC-1 protein (Yang et al.) with a reference that teaches β-galactosidase fused to a TAT peptide. Applicants submit that a *prima facie* case of obviousness has not been established based on this combination at least because no motivation exists, either in the cited references or in the knowledge generally available to one of ordinary skill in the art at the time of the invention, to combine these two references to arrive at the claimed chimeric protein. Specifically, at the time of the invention, one would not have imagined that because TAT fused to β-galactosidase was able to transduce the blood-brain barrier (as taught in Schwarze et al.), that TAT, when fused to APOBEC-1, would have had the ability to enter a cell, be properly re-folded, and retain the ability to edit mRNA encoding apoliprotein B. The β-galactosidase of Schwarze et al. did not carry out any function, or produce any resulting product when coupled to TAT. Its presence was merely detected. In sharp contrast, the claimed chimeric protein is able to edit mRNA after transducing the cell. One of skill in the art would not have supposed that APOBEC-1 could have retained such functionality when coupled to TAT based on the teachings of Schwarze et al. and Yang et al.

Thus, the Action has failed to provide any evidence that any disclosure exists in the art that would destroy the novelty or inventive step of this common technical feature and thereby destroy the inventive concept. Thus, the Action does not meet the requisite burden for

establishing a lack of unity of invention. Accordingly, Applicant submits that all of the pending claims possess unity of invention and, therefore, request reconsideration and modification or withdrawal of the restriction.

Election of Species

The Office Action also alleges that the application contains claims directed to more than one category of species of the generic invention. The Office Action also required that if any of groups I-II, IV-VI, or VIII-XI were elected, that one species of each of groups A-C also be elected.

A. genus of deaminase:

i. CEM15 (claims 5-8, 21);

ii. CEM15 mimetic (claim 27);

iii. activation-induced deaminase (AID) (claims 47, 51, 52);

B. genus of protein transducing domain:

1. HIV Tat protein (claims 2-4 or 48-50);

2. poly-arginine peptide (claim 2 or 48);

3. poly-lysine peptide (claim 2 or 48);

4. third alpha helix of antennapedia homeodomain protein (claim 2 or 48);

5. HSV-1 virion protein (VP) 22 (claim 2 or 48);

6. HIV-1 Vpr protein (claim 2 or 48);

C. genus of the third peptide of which the chimeric protein is comprised:

a. hemagglutinin epitope tag (claims 9-10 or 58-59);

b. polyhistidine tag (claim 11 or 60);

c. protein cleavage site (claim 15); and

d. solubility enhancer (claims 12-14 or 53-57).

In response, applicants elect from Group A, i (CEM15); from Group B, 1 (HIV TAT protein); and from Group C, a (hemagglutinin epitope tag) with traverse.

Applicants specifically traverse Group C, which the Action refers to as "genus of the third peptide of which the chimeric protein is comprised." Applicants respectfully point out that there is no "third peptide," rather those components found in Group C are various features that can be included in the chimeric protein. Furthermore, they are not independent or distinct species, as there is no genus relating all of these "species" together. Therefore, it is not appropriate to require a species election when no generic genus for such species exists (see MPEP §806.04). Applicant notes that, upon allowance of a generic claim, Applicant will be entitled to consideration of additional species that are written in dependent form or otherwise include all limitations of an allowed generic claim, as provided by 37 C.F.R. 1.141.

Favorable consideration of claims 1-124 is earnestly solicited.

A credit card payment submitted via EFS Web in the amount of $60.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(1), and a Request for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby

authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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